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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,449	03/28/2005	Kazuyuki Yamane	10936-84	8257
24256 7590 09/12/2007 DINSMORE & SHOHL, LLP 1900 CHEMED CENTER 255 EAST FIFTH STREET CINCINNATI, OH 45202			EXAMINER TOSCANO, ALICIA	
			ART UNIT . 1712	PAPER NUMBER
			MAIL DATE 09/12/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/529,449

Applicant(s)

YAMANE ET AL.

Examiner

Alicia M. Toscano

Art Unit

1712

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 04 September 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: _____.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's arguments are not persuasive. Applicant argues that the required 1.35 increase in molecular weight is not disclosed by Matsumoto. Applicant again draws attention to the examples of Matsumoto which show a small increase (Ex 1) or a small decrease (Ex 2, 5 and 6) in the specific viscosity ratio of end capped to non-endcapped PLLA and uses this as evidence that the molecular weight has not been increased. Applicant submits pages from the Principles of Polymer Chemistry and Concise Encyclopedia of Polymer Science and Engineering as evidence that the specific viscosity and molecular weight are directly linked.

The Examiner disagrees. The Examiner has addressed this argument before and specifically asked for data to the contrary of Matsumoto. Applicant's arguments drawn to the specific viscosity are not convincing because the data itself does not make sense. When Matsumoto end caps the polymer, the molecular weight must increase. There is no disclosure, evidence or scientific reason that the molecular weight would decrease. Thusly, since Matsumoto discloses a decrease in specific viscosity the Examiner believes that the different interaction between the solution and newly endcapped polymer must affect the viscosity readings. Matsumoto is using the specific viscosity readings to further compare the hydrolysis rate of the polymers when subjected to hot water. Matsumoto is not concerned with the molecular weight or a molecular weight increase to prove end capping has occurred. Matsumoto relies on carboxyl equivalents as proof endcapping occurs. For these reasons the Examiner can not draw clear conclusions on Matsumoto's examples. The rejection thusly stands.

Applicant further argues that Matsumoto does not teach reacting the end-groups to completion, an argument the Examiner relied upon in the rejection. As evidence to this Applicant draws attention of [0021] wherein Matsumoto discloses the amount of unreacted end capping agent to be 2-5 wt%. The Examiner had previously used this amount as the amount of end capping agent added to the composition.

Though the Examiner erred in the position that 2-5 wt% of end capping agent is used in the composition, Matsumoto's examples show that the reaction was taken to near completion, specifically comparing Comp Ex 1 (33 eq/10-3 kg residual carboxyl groups) to Ex 6 (1 residual carboxyl equivalent after reaction with end capping agent). Further, in order to have 2-5 wt% excess end capping agent, one must use at least 2-5 wt% of said agent in the composition. Which meets the compositional requirements of Applicant's Claims. Matsumoto does disclose fully reacting the composition, as evidenced by Ex 6.

It is thusly still unclear to the why the molecular weight increase is not inherent. Examiner again requests data to the contrary.

Applicant argues the MW ranges disclosed in [0010] of Matsumoto are for polylactic acid and not polyglycolic acid, as required by the Claims. Though true, Matsumoto discloses polylactic and polyglycolic acid to be functional equivalent polymers to be used in the invention, and thusly one would use the same MW ranges disclosed for the polylactic acid. Applicant draws attention to the lower MW polyglycolic acid used in the examples, however the Examiner notes that the patent cannot be limited to the examples. The position of the Examiner is that one would use the ranges taught of the polylactic acid since polylactic acid and polyglycolic acid are functional equivalents.

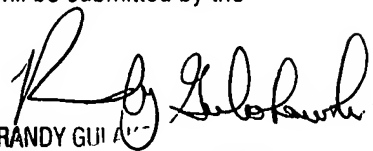
Applicant argues that the reaction conditions of Matsumoto fail to suggest the production of a high molecular weight PGA, as required in Claim 11. The Examiner argued that the reaction time and temperature are result effective variables but Applicant argues that since Matsumoto provides no teaching of chain extending that the reaction time/temperature limitation is not met.

The Examiner disagrees. Since the Applicant has not shown data that the process of Matsumoto does not inherently result in chain lengthening, as previously requested, it is still the position of the Examiner that chain lengthening inherently occurs and one would manipulate the time and temperature for reasons previously set forth.

Applicant argues Bonsignore fails to disclose the use of polyglycolic acid and that Bonsignore does not describe the conditions under which the reaction takes place, therefor Bonsignore does not meet the chain lengthening requirements. Applicant argues Matsumoto does not resolve said deficiencies. Further, Applicant argues the Examiner incorrectly cited the wt% of [0021].

The Examiner disagrees. Bonsignore discloses polyglycolic acid, as set forth in each action in Column 3 Line 62. There is no mention of polyglycolic copolymers, thusly it would comprise 100% glycolic acid units, which meets the limitations of the Claim. If Applicant wishes to again pursue this argument the Examiner requests that Applicant acknowledge and address the polyglycolic acid of Column 3 Line 62 when making said arguments. Bonsignore does not disclose reaction conditions but Matsumoto does, as set forth. The rejection thusly stands. Though the Examiner erred in the amount of end capping agent in Matsumoto, the examples disclose the use of an amount within applicants range, and further, in order to have an excess of 2-5 wt% one must use 2-5 wt% in the composition.

The Examiner further notes that Applicant did not submit a complete translation of Matsumoto (for example paragraphs [0011]-[0017] are missing. A complete translation has been requested (but not yet received) through the USPTO translator and will be submitted by the Examiner in any subsequent correspondence.


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